



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND  
POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

25/FEB/2015

MEMORANDUM

Subject: Acute Toxicity Review for EPA File Symbol 59639-ENE

Name of Pesticide Product: Zeal SC Miticide  
EPA Reg. No.: 59639-ENE  
DP Barcode: D420374  
Decision No.: 491097  
Action Code: R320  
PC Code: 107091 (etoxazole)

From: Eugenia McAndrew, Biologist *E. McAndrew*  
Chemistry, Inerts, Toxicology Assessment Branch  
Registration Division (7505P)

*H. Haslam*  
TOXICOLOGIST

To: Jacquelyn Marchese, RM Team 07  
Invertebrate and Vertebrate Branch 3  
Registration Division (7505P)

Applicant: Valent U.S.A. Corporation  
1600 Riveria Ave., Suite 200  
Walnut Creek, CA 94596-8025

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Ettoxazole	31.7
<u>Other Ingredient(s):</u>	<u>68.3</u>
Total:	100.0%

**ACTION REQUESTED:** The Risk Manager requests a review of six acute toxicity studies submitted to support the registration of EPA File Symbol 59639-ENE.

**BACKGROUND:** Valent U.S.A. has submitted six acute toxicity studies (MRID Nos. 492456-03 to -08) to support the registration of Zeal SC Miticide, EPA File Symbol 59639-ENE. This product is a new SC formulation of a contact acaricide being developed for control of mites on various crops. The active ingredient is etoxazole. The submission includes a label, a basic CSF dated November 25, 2013, alternate CSF # 1 dated November 20, 2013 and a company letter. The product chemists in the Chemistry, Inerts, Toxicology Assessment Branch must review and accept the basic and alternate # 1 CSFs.

**GLP:** Yes

**DEVIATIONS:** None

**LABELING:**

**PRODUCT ID #:** 059639-00202

**PRODUCT NAME:** Zeal SC Miticide

**PRECAUTIONARY STATEMENTS**

**SIGNAL WORD:** CAUTION  
(optional)

**Hazards to Humans and Domestic Animals:**

Wear: Long-sleeved shirt and long pants, socks, shoes, and gloves.

**First Aid:** No statements are required. Category III statements may be used.

**User Safety Recommendations:**

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. ✓
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. ✓
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change clothing. ✓



### DATA EVALUATION RECORD

**Product Reg. No.:** 59639-ENE

**Product Name:** Zeal SC Miticide

**1. DP BARCODE:** 420374

**2. PC CODE:** 107091

**3. CURRENT DATE:** February 25, 2015

**4. TEST MATERIAL:** Zeal Miticide SC [Lot # V13J-1927-1; PSL Reference # 140115-5H; 39% Etoxazole; pH neutral (6-8); density 1.037 g/mL; off-white emulsion; administered as received]

Study/Species/Lab Study # /Date	MRID	Results	Tox Cat	Core Grade
Acute oral toxicity / rat Product Safety Labs Study #38041/March 20, 2014 OCSPP 870.1100; OECD 425	49245603	LD <sub>50</sub> Females > 5000 mg/kg  3 animals tested at 5000 mg/kg  All animals survived and gained weight. No clinical signs were observed and no gross abnormalities were observed at necropsy.	IV	A
Acute dermal toxicity / rat Product Safety Labs Study #38042/March 18, 2014 OCSPP 870.1200; OECD 402	49245604	LD <sub>50</sub> > 5000 mg/kg (both sexes)  All animals survived. One female lost weight by day 7 but all animals gained weight by day 14. Dermal irritation (erythema) was observed at 4 dose sites on days 1-2. Desquamation was noted at 2 dose sites on days 2-5. No gross abnormalities were observed at necropsy.	IV	A
Acute inhalation toxicity / rat Product Safety Labs Study #38043/March 20, 2014 OCSPP 870.1300; OECD 403	49245605	LC <sub>50</sub> > 2.09 mg/L (both sexes)  MMAD: 2.73, 3.00 GSD: 2.49, 2.57  All animals survived. Five animals	IV	A

		lost weight by day 1 and 3 animals lost or failed to gain weight by day 3 but all gained weight thereafter through day 14. All rats exhibited irregular respiration with recovery by day 3. One male exhibited moist rales immediately after removal from the chamber tube. No gross abnormalities were noted at necropsy.		
Primary eye irritation / rabbit Product Safety Labs Study #38044/March 21, 2014 OCSPP 870.2400; OECD 405	49245606	3 males tested; ocular anesthetic used No corneal opacity or iritis were observed. The only irritation noted was a score of 1 for discharge (not a positive effect) in 2/3 eyes at 1 hr which cleared by 24 hrs.  MMTS = 1.3 at 1 hour	IV	A
Primary dermal irritation / rabbit Product Safety Labs Study #38045/March 21, 2014 OCSPP 870.2500; OECD 404	49245607	PDI = 01.3 1 male and 2 females tested  Very slight erythema and very slight edema were noted at all dose sites 30-60 minutes after patch removal. The irritation decreased with time. At 72 hrs very slight erythema was still present at 2 dose sites. All sites were free of irritation on day 7. Desquamation was noted at all sites between 72 hrs and day 7.	IV	A
Dermal sensitization/ mouse/rLLNA Product Safety Labs Study #38046/March 18, 2014 OCSPP 870.2600; OECD 429	49245608	Negative  Concentration of 100% tested Stimulation Index Value = 1.69  Results of concurrent positive control study are acceptable.	--	A

**Core Grade Key: A = Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap  
W = Waived**